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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/944,807 | 08/31/2001 | Birgit Jung | 1/1144 | 1468 |

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| EXAMINER |
|---|
| KEMMERER, ELIZABETH |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1646 | |

DATE MAILED: 10/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/944,807 | JUNG ET AL. | |
| | Examiner | Art Unit | |
| | Elizabeth C. Kemmerer, Ph.D. | 1646 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *31 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-64* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10 (in part), drawn to method or determining whether a substance is an activator or an inhibitor of an ILM receptor, wherein the receptor comprises SEQ ID NO: 2 (or generically claimed variants thereof), classification dependent upon structure of recited substance.

II. Claims 1-8 (in part), drawn to method or determining whether a substance is an activator or an inhibitor of an ILM receptor, wherein the receptor comprises SEQ ID NO: 21 (or generically claimed variants thereof), classification dependent upon structure of recited substance.

III. Claims 1-8 (in part), drawn to method or determining whether a substance is an activator or an inhibitor of an ILM receptor, wherein the receptor comprises SEQ ID NO: 6 (or generically claimed variants thereof), classification dependent upon structure of recited substance.

IV. Claims 1-8 (in part), drawn to method or determining whether a substance is an activator or an inhibitor of an ILM receptor, wherein the receptor comprises SEQ ID NO: 12 (or generically claimed variants thereof), classification dependent upon structure of recited substance.

V. Claims 1-8 (in part), drawn to method or determining whether a substance is an activator or an inhibitor of an ILM receptor, wherein the receptor

comprises SEQ ID NO: 4 (or generically claimed variants thereof), classification dependent upon structure of recited substance.

VI. Claims 1-8 (in part), drawn to method or determining whether a substance is an activator or an inhibitor of an ILM receptor, wherein the receptor comprises SEQ ID NO: 8 (or generically claimed variants thereof), classification dependent upon structure of recited substance.

VII. Claims 1-8 (in part), drawn to method or determining whether a substance is an activator or an inhibitor of an ILM receptor, wherein the receptor comprises SEQ ID NO: 10 (or generically claimed variants thereof), classification dependent upon structure of recited substance.

VIII. Claims 11-25 (in part), drawn to method of determining an expression level of an ILM receptor wherein the ILM receptor comprises SEQ ID NO: 2 (or generically claimed variants thereof), classified in class 435, subclass 7.1, for example.

IX. Claims 11-18 and 21-25 (in part), drawn to method of determining an expression level of an ILM receptor wherein the ILM receptor comprises SEQ ID NO: 21 (or generically claimed variants thereof), classified in class 435, subclass 7.1, for example.

X. Claims 11-18 and 21-25 (in part), drawn to method of determining an expression level of an ILM receptor wherein the ILM receptor comprises SEQ ID NO: 6 (or generically claimed variants thereof), classified in class 435, subclass 7.1, for example.

XI. Claims 11-18 and 21-25 (in part), drawn to method of determining an expression level of an ILM receptor wherein the ILM receptor comprises SEQ ID NO: 12 (or generically claimed variants thereof), classified in class 435, subclass 7.1, for example.

XII. Claims 11-18 and 21-25 (in part), drawn to method of determining an expression level of an ILM receptor wherein the ILM receptor comprises SEQ ID NO: 4 (or generically claimed variants thereof), classified in class 435, subclass 7.1, for example.

XIII. Claims 11-18 and 21-25 (in part), drawn to method of determining an expression level of an ILM receptor wherein the ILM receptor comprises SEQ ID NO: 8 (or generically claimed variants thereof), classified in class 435, subclass 7.1, for example.

XIV. Claims 11-18 and 21-25 (in part), drawn to method of determining an expression level of an ILM receptor wherein the ILM receptor comprises SEQ ID NO: 10 (or generically claimed variants thereof), classified in class 435, subclass 7.1, for example.

XV. Claims 26-32 (in part), drawn to a test system kit comprising an ILM receptor, wherein the ILM receptor comprises SEQ ID NO: 2 (or generically claimed variants thereof), classified in class 530, subclass 350, for example.

XVI. Claims 26-28, 31 and 32 (in part), drawn to a test system kit comprising an ILM receptor, wherein the ILM receptor comprises SEQ ID NO: 21 (or

generically claimed variants thereof), classified in class 530, subclass 350, for example.

XVII. Claims 26-28, 31 and 32 (in part), drawn to a test system kit comprising an ILM receptor, wherein the ILM receptor comprises SEQ ID NO: 6 (or generically claimed variants thereof), classified in class 530, subclass 350, for example.

XVIII. Claims 26-28, 31 and 32 (in part), drawn to a test system kit comprising an ILM receptor, wherein the ILM receptor comprises SEQ ID NO: 12 (or generically claimed variants thereof), classified in class 530, subclass 350, for example.

XIX. Claims 26-28, 31 and 32 (in part), drawn to a test system kit comprising an ILM receptor, wherein the ILM receptor comprises SEQ ID NO: 4 (or generically claimed variants thereof), classified in class 530, subclass 350, for example.

XX. Claims 26-28, 31 and 32 (in part), drawn to a test system kit comprising an ILM receptor, wherein the ILM receptor comprises SEQ ID NO: 8 (or generically claimed variants thereof), classified in class 530, subclass 350, for example.

XXI. Claims 26-28, 31 and 32 (in part), drawn to a test system kit comprising an ILM receptor, wherein the ILM receptor comprises SEQ ID NO: 10 (or generically claimed variants thereof), classified in class 530, subclass 350, for example.

XXII. Claims 33-49 (in part), drawn to a substance and a composition comprising same, wherein the substance is an activator or an inhibitor of an ILM receptor, wherein the ILM receptor comprises SEQ ID NO: 2 (or generically claimed variants thereof), classification dependent upon structure of recited substance.

XXIII. Claims 33-35, 38-40 and 43-47 (in part), drawn to a substance and a composition comprising same, wherein the substance is an activator or an inhibitor of an ILM receptor, wherein the ILM receptor comprises SEQ ID NO: 21 (or generically claimed variants thereof), classification dependent upon structure of recited substance.

XXIV. Claims 33-35, 38-40 and 43-47 (in part), drawn to a substance and a composition comprising same, wherein the substance is an activator or an inhibitor of an ILM receptor, wherein the ILM receptor comprises SEQ ID NO: 6 (or generically claimed variants thereof), classification dependent upon structure of recited substance.

XXV. Claims 33-35, 38-40 and 43-47 (in part), drawn to a substance and a composition comprising same, wherein the substance is an activator or an inhibitor of an ILM receptor, wherein the ILM receptor comprises SEQ ID NO: 12 (or generically claimed variants thereof), classification dependent upon structure of recited substance.

XXVI. Claims 33-35, 38-40 and 43-47 (in part), drawn to a substance and a composition comprising same, wherein the substance is an activator or an

inhibitor of an ILM receptor, wherein the ILM receptor comprises SEQ ID NO: 4 (or generically claimed variants thereof), classification dependent upon structure of recited substance.

XXVII. Claims 33-35, 38-40 and 43-47 (in part), drawn to a substance and a composition comprising same, wherein the substance is an activator or an inhibitor of an ILM receptor, wherein the ILM receptor comprises SEQ ID NO: 8 (or generically claimed variants thereof), classification dependent upon structure of recited substance.

XXVIII. Claims 33-35, 38-40 and 43-47 (in part), drawn to a substance and a composition comprising same, wherein the substance is an activator or an inhibitor of an ILM receptor, wherein the ILM receptor comprises SEQ ID NO: 10 (or generically claimed variants thereof), classification dependent upon structure of recited substance.

XXIX. Claims 50-64 (in part), drawn to a method of administering a substance, wherein the substance is an activator or an inhibitor of an ILM receptor, wherein the ILM receptor comprises SEQ ID NO: 2 (or generically claimed variants thereof), classification dependent upon structure of recited substance.

XXX. Claims 50-52 and 55-62 (in part), drawn to a method of administering a substance, wherein the substance is an activator or an inhibitor of an ILM receptor, wherein the ILM receptor comprises SEQ ID NO: 21 (or

generically claimed variants thereof), classification dependent upon structure of recited substance.

XXXI. Claims 50-52 and 55-62 (in part), drawn to a method of administering a substance, wherein the substance is an activator or an inhibitor of an ILM receptor, wherein the ILM receptor comprises SEQ ID NO: 6 (or generically claimed variants thereof), classification dependent upon structure of recited substance.

XXXII. Claims 50-52 and 55-62 (in part), drawn to a method of administering a substance, wherein the substance is an activator or an inhibitor of an ILM receptor, wherein the ILM receptor comprises SEQ ID NO: 12 (or generically claimed variants thereof), classification dependent upon structure of recited substance.

XXXIII. Claims 50-52 and 55-62 (in part), drawn to a method of administering a substance, wherein the substance is an activator or an inhibitor of an ILM receptor, wherein the ILM receptor comprises SEQ ID NO: 4 (or generically claimed variants thereof), classification dependent upon structure of recited substance.

XXXIV. Claims 50-52 and 55-62 (in part), drawn to a method of administering a substance, wherein the substance is an activator or an inhibitor of an ILM receptor, wherein the ILM receptor comprises SEQ ID NO: 8 (or generically claimed variants thereof), classification dependent upon structure of recited substance.

XXXV. Claims 50-52 and 55-62 (in part), drawn to a method of administering a substance, wherein the substance is an activator or an inhibitor of an ILM receptor, wherein the ILM receptor comprises SEQ ID NO: 10 (or generically claimed variants thereof), classification dependent upon structure of recited substance.

The inventions are distinct, each from the other because of the following reasons:

Each group of inventions I-VII, VIII-XIV, XV-XXI, XXII-XXVIII, and XXIX-XXXV differ by the recited sequence of the ILM receptor. Each invention of each group is independent and distinct from the others, because the search required for any one sequence is not co-extensive with the search required for any of the other sequences. The search involves not only the sequence databases, but the publications databases as well. Therefore, a search and examination of multiple sequences in a method or product claim presents an undue search burden on the examiner.

Inventions XXII-XXVIII and XXIX-XXXV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the substances of Inventions XXII-XXVIII can be used to label or purify ILM receptors.

Inventions I-VII and XXII-XXVIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1)

that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the substances of XXII-XXVIII can be made synthetically.

Inventions XV-XXI and VIII-XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the kits comprising the receptors can be used to label or isolate ligands.

The remaining pairs of Inventions are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the product of each remaining Invention pair is not required by the method of each remaining Invention pair.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements and different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D. whose telephone number is (703) 308-2673. The examiner can normally be reached on Mon. - Thurs., 6:30 to 4:00, and alternate Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne L. Eyler, Ph.D. can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Elizabeth C. Kemmerer

ECK
October 17, 2002

ELIZABETH KEMMERER
PRIMARY EXAMINER